IDAHO DEPARTMENT OF HEALTH & WELFARE

Disease Bulletin

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Idaho Public Health Response to a Multi-State Outbreak of Fungal Meningitis Associated with Contaminated Steroids

On Saturday, September 29, 2012, the Idaho Division of Public Health was alerted to a joint CDC/FDA investigation of a cluster of clinical meningitis cases following spinal injection procedures for pain. A week earlier, the Tennessee Department of Health had been notified of a patient with clinically-diagnosed meningitis following an epidural steroid injection (ESI) at a Tennessee ambulatory surgical center. The fungus *Aspergillus fumigatus* was isolated from CSF. Subsequent outreach demonstrated nine additional ill patients with similar clinical presentation, including one at a facility in North Carolina. All patients had received at least one ESI with methylprednisolone acetate (MPA) distributed by New England Compounding Center (NECC) in Framingham, MA that was recalled September 26.

Public health response and outreach to providers

A list of providers in the United States who had received one or more of the lots of recalled MPA was received from CDC. CDC recommended all patients that had an ESI at one of the clinics that received any of the three recalled lots (05212012@68, 0629212@26, 08102012@51) of MPA from NECC be contacted to determine their clinical status. Two providers in Idaho received the recalled ("hot lots") of MPA. They were contacted via FAX and phone, alerted to the investigation, and were provided with details about the known clinical picture of identified patients. Providers were encouraged to perform in-person follow-up with patients if possible because symptoms were varied and insidious. Infectious disease physicians and public health district epidemiologists were notified via email of the investigation, Idaho's planned response, and information on how to contact public health officials of any possible cases.

Over the next week, daily follow up with the two Idaho facilities was conducted by Division of Public Health staff. Facilities in Idaho proactively contacted patients that had received an ESI with MPA from the hot lots. An October 5 press release alerted the public to what symptoms might be and urged them to contact their providers if they received and ESI from one of the two Idaho facilities.

On October 6, NECC voluntarily recalled all products distributed. In addition to the two Idaho facilities that received the hot lots of MPA, an additional nine Idaho facilities had received other injectable products from NECC, including betamethasone and triamcinolone. Those facilities were contacted and encouraged to follow-up with patients to evaluate their health status.

For purposes of the public health investigation, a case of infection linked to this outbreak was considered in any person who:

1. Received an injection with MPA produced by NECC,
2. Developed fungal meningitis or non-bacterial and non-viral meningitis[1] of sub-acute onset, and
3. Had an epidural injection on and after May 21, 2012.

As of 2/22/2013, infections have been diagnosed in 707 patients. The predominant fungus identified in patients continues to be *Exserohilum rostratum*, although the index case had a laboratory-confirmed *A. fumigatus* infection.

[1] Clinically diagnosed meningitis meaning one of more of the following symptoms: headache, fever, stiff neck, or photophobia and a cerebrospinal fluid (CSF) profile showing pleocytosis (>5 white blood cells, adjusting for presence of red blood cells) regardless of glucose or protein levels.

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These fungi are common in the environment; infections are usually seen in immunocompromised persons and are not transmissible person to person.

Idaho-specific case investigations

During the week ending October 6, nine patients that received ESIs reported symptoms and were further evaluated. Two additional patients had lumbar punctures to rule out infection. Of these 11 patients, 1 female was hospitalized over the weekend, had normal CSF, and was released; a male patient was hospitalized overnight due to elevated CSF protein, but was then released.

On October 10, the Idaho Public Health Medical Director was notified of a male in his 70s who met the CDC outbreak surveillance definition for meningitis, although ultimately the treating physician decided this patient did not have meningitis.

Forty follow up appointments with patients exposed to the contaminated products were conducted by Idaho physicians the weeks ending October 13 and October 20 to ensure they were in good health and to follow up on any mild symptoms. These follow up visits sometimes identified additional persons with mild or nonspecific symptoms requiring further investigation to rule out subtle clinical disease. Evaluations included clinical examination, MRI, and other studies. As of February 22, no additional cases have been identified in Idaho.

Product recalls and investigation

CDC and FDA have isolated *E. rostratum* in unopened vials of MPA from two of the three implicated lots (06292012@26 and 08102012@51). The laboratory confirmation further links steroid injections from these lots from NECC to the outbreak. Testing on the third implicated lot continues.

CDC and FDA have identified additional microbial contamination of non-MPA NECC injectable products including betamethasone, triamcinolone, and cardioplegia solution. Identified organisms include *A. tubingensis, A. fumigatus, Bacillus circulans, B. firmus, B. flexus, B. halmapalus/horikoshii, B. idriensis, B. lentus, B. niabensis, B. niacin, B. pumilus, B. simplex, Brevibacillus choshinensis, Cladosporium* sp., *Kocuria rosea, Lysinibacillus* sp., *Paenibacillus barengoltzii/timonensis, P. pabuli/amolyticus, and Penicillium* sp. Although rare, some of the identified *Bacillus* species can be human pathogens. Some of the fungal organisms identified, particularly *A. fumigatus*, are known to cause disease in humans. It is not known how product contamination with these organisms could affect patients clinically.

On October 31, NECC's parent company, Ameridose, LLC, based in Westborough, MA voluntarily recalled all unexpired products that company had in circulation. FDA investigation of both NECC and Ameridose continues. For information on the ongoing outbreak investigation and product recalls, visit the CDC website at www.cdc.gov/hai/outbreaks/meningitis.html and FDA website at www.fda.gov/Drugs/DrugSafety/FungalMeningitis/default.htm.

This is by far the largest outbreak of fungal meningitis linked to injectable pharmaceutical products used in medical procedures. Federal congressional hearings and FDA investigations into the activities of NECC are ongoing and have expanded into regulatory oversight of compounding pharmacies. The Idaho Board of Pharmacy is collaborating with other state boards of pharmacy through the National Association of Boards of Pharmacy to formulate solutions to better identify companies potentially blurring the line between dispensing compounded medication and distributing manufactured product. The Idaho Board of Pharmacy has inspected, and subsequently surveyed, all Idaho sterile compounding pharmacies, penned responses to dozens of questions posed by Congress, testified at an FDA hearing, held various informal meetings with Idaho compounders, and is engaged in negotiated rulemaking for the current legislative session.

Maternal Hepatitis B Infection and Prevention of Perinatal Hepatitis B through Case Management

Background

During 2001–2011, an average of 16 births per year to women infected with Hepatitis B virus (HBV) were reported in Idaho. Transmission of HBV to infants from infected mothers is of particular concern. Infants infected at birth are more likely than older children and adults to suffer clinical complications and serious liver disease.[1] Without intervention, perinatal transmission of HBV from mother to infant during pregnancy and birth is high (approximately 80%–90%), but appropriate prophylaxis can decrease the probability of transmission by up to 95%.[2] Hepatitis B immune globulin (HBIG) and Hepatitis B vaccine are recommended to be administered to exposed infants within 12 hours of birth.

Prevention of perinatal transmission

Public Health Districts and Idaho's Perinatal Hepatitis B Prevention Program provide case management of pregnant HBV-infected women and exposed infants to ensure that HBIG and hepatitis B vaccine are administered at birth and to follow up on post-vaccination serologic testing of infants at 9–12 months of age. During 2001–2010 in Idaho, 91% of case-managed infants received appropriate prophylaxis at birth, but only 34% of infants had documented results of post-vaccination serology. Improved coordination among prenatal care providers, delivery providers, and pediatric providers could improve the proportion of exposed infants tested. Not only is serologic testing important to determine if viral transmission has occurred, it also provides evidence of an appropriate immune response to the completed Hepatitis B vaccine series.

Because not all HBV infections among pregnant women are identified before

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delivery, and prenatal screening records are not always available during delivery, the universal birth dose of hepatitis B vaccine continues to serve as a safety net for preventing transmission to infants. Data suggest that the 3-dose series of HBV vaccine can prevent infection by as much as 75%–90%.[2] Standing orders or protocols for screening and administration of immune globulin and vaccine can help to ensure that infants born to potentially infected women are protected.

Underreporting of hepatitis B during pregnancy

Both acute and chronic HBV infection are reportable to Idaho public health officials. Based on Idaho demographic data and national HBV prevalence data, the Centers for Disease Control and Prevention (CDC) estimates that the number of hepatitis B surface antigen (HBsAg)-positive pregnant women in Idaho might be underreported by 50%–75%; however, a recent evaluation of perinatal hepatitis B surveillance in Idaho suggests that the number of unreported cases is likely more in the range of 5%–10%.

HBV infection might be undetected if prenatal screening is not performed. Screening using the surface antigen test early in prenatal care is recommended as standard of care by American College of Obstetricians and Gynecologists,[2] the United States Preventive Services Task Force,[3] the American Association for the Study of Liver Diseases,[4] and CDC;[5] however, prenatal care providers might not always screen women for HBV, especially if a woman returns to the same provider after a pregnancy and she was previously screened for HBV infection. Women of unknown HBV infection status who present at delivery facilities might not be screened immediately for HBV infection as recommended.

Idaho public health are not always informed when a woman chronically infected with HBV becomes pregnant, either because no HBV testing was done at the time of pregnancy or because the mother's chronic HBV case was previously reported. Notification to public health officials about all pregnancies in HBV-infected women helps ensure timely provision of HBIG and Hepatitis B vaccine within 12 hours of birth and public health case management services for the infant.

References

[1] Centers for Disease Control and Prevention. Hepatitis B. In: Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book). Atkinson W, Wolfe S, Hamborsky J, editors. 12th ed. Washington, DC: Public Health Foundation, 2011. www.cdc.gov/vaccines/pubs/pinkbook/index.html

[2] American College of Obstetricians and Gynecologists (ACOG). *Viral hepatitis in pregnancy (ACOG practice bulletin no. 86)*. Washington, D.C.: American College of Obstetricians and Gynecologists (ACOG); October 15, 2007.

[3] U.S. Preventive Services Task Force. Screening for hepatitis B virus infection in pregnancy: U.S. Preventive Services Task Force reaffirmation recommendation statement. *Ann Intern Med*. 2009;150(12):869-73, W154.

[4] Lok AS, McMahon BJ. Chronic hepatitis B: update 2009. *Hepatology.* 2009;50(3):661-2.

[5] Weinbaum CM, Williams I, Mast EE, Wang SA, Finelli L, Wasley A, Neitzel SM, Ward JW. Recommendations for identification and public health management of persons with chronic hepatitis B virus infection. *MMWR Recomm Rep*. 2008;57(RR-8):1-20.

Meaningful Use of Electronic Health Records for Syndromic Surveillance in Idaho using BioSense 2.0

The Health Information Technology for Economic and Clinical Health Act (HITECH) includes provisions for a financial incentive to eligible providers and hospitals for adopting use of qualified, certified electronic health record (EHR) systems that are used in a meaningful way ("Meaningful Use") to achieve significant improvements in care. Payments are administered by the federal Medicare and state Medicaid programs with oversight by the federal Centers for Medicare and Medicaid Services (CMS). Rules released by CMS July 2010 for Stage 1 and August 2013 for Stage 2 (beginning in 2014) define criteria for EHR certification and eligibility to receive incentive payments. Eligible hospitals and providers can meet requirements by submitting immunization, reportable disease laboratory result, and syndromic surveillance data electronically to public health agencies.

Stage 1 of Meaningful Use includes submission of data for syndromic surveillance as one of the public health reporting menu options an eligible hospital or provider can choose to qualify for incentive payments. This reporting becomes a core requirement for eligible hospitals in Stage 2, but remains optional for eligible providers. In contrast to other public health surveillance systems, syndromic surveillance uses near real-time patient data to enable the timely assessment of community data. Syndromic surveillance can help public health track the health of communities, maintain situational awareness during outbreaks, more closely monitor seasonal increases or decreases of known illnesses, identify health effects of events such as poor air quality, and detect health events early.

Syndromic surveillance capacity in Idaho

The Idaho Department of Health and Welfare Division of Public Health (DPH) has received funding to build syndromic surveillance capacity through use of BioSense 2.0 to capture emergency department data for syndromic surveillance. Data from hospital EHRs are sent using secure data transmission methods to BioSense 2.0 (www.cdc.gov/biosense/biosense20.html), an application designed by the Centers for Disease Control and Prevention, using a standardized format. Algorithms categorize the chief complaint and diagnosis data into syndrome classes that can be analyzed by public health to enhance the monitoring of population health. The main goal of the first year of funding is to collaborate with at least five Idaho hospitals to begin

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An electronic version of the Idaho Reportable Rules may be found at http://adminrules.idaho.gov/rules/current/16/0210.pdf.

Current and past issues are archived online at www.idb.dhw.idaho.gov.

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transmitting emergency department data to BioSense 2.0 by August 2013. Panhandle Health District and Southwest District Health are participating in a pilot project to engage with hospitals in their district on BioSense 2.0 activities. As eligible hospitals implement Meaningful Use Stage 2 activities, the DPH anticipates enrolling additional facilities. Once the number of hospitals contributing data is sufficient to obscure facility identification, views of aggregate data may be shared with DPH-approved public health stakeholders. Throughout the project, DPH will consult the Governor's Health Care Council Health Information Technology (HIT) Workgroup to develop policies for ensuring appropriate data aggregation and security.

For hospitals interested in providing emergency department data for syndromic surveillance, DPH has guidance available online: go to www.epi.idaho.gov and click on "Public Health Meaningful Use Reporting" on the left side of the screen. Eligible hospitals can email PublicHealthMU@dhw.idaho.gov for information related to Meaningful Use public health reporting, including syndromic surveillance. DPH is not currently accepting data from eligible providers for syndromic surveillance.

Idaho Disease Bulletin Available Electronically

The Idaho Disease Bulletin (IDB) website (www.IDB.dhw.idaho.gov) includes searchable indices of issues from the last 10 years, the ability for readers to suggest topics, and the ability for readers to sign up to receive an electronic copy of the IDB. If you would like to receive am email with a link to new issues of the IDB please go to www.IDB.dhw.idaho.gov to submit a request or send an email to IDB@dhw.idaho.gov.